California Health and Human Services Agency
Committee for the Protection of Human Subjects

New Project Application and Review Checklist

Date: _____
Project Title: _____

Institutional Affiliation:_____
Principal Investigator (PI): _____
Mailing Address: _____

_____
Telephone: _____ Fax: _____ E-mail: _____

SHADED AREA IS FOR CPHS STAFF USE ONLY
Project Number:
Reviewer:
Date to Reviewer:
Due Date:

Have you included the following (please check)?

All Projects:

Staff Reviewer:

- ☐ Cover Letter — ☐ Yes ☐ No
- ☐ New Project Application and Review Checklist — ☐ Yes ☐ No
- ☐ Project Protocol — ☐ Yes ☐ No
- ☐ Signature of P.I.(s) on New Project Application and Review Checklist — ☐ Yes ☐ No
- ☐ Signatures of P.I. and Responsible Official on Project Protocol — ☐ Yes ☐ No
- ☐ C.V. of Principal Investigator(s) — ☐ Yes ☐ No

Other Possible Items (check if submitted in research proposal):

- ☐ Checklist for Research Involving Children — ☐ Yes ☐ No
- ☐ Checklist for Research Involving Pregnant Women and Fetuses — ☐ Yes ☐ No
- ☐ Checklist for Research Involving Neonates — ☐ Yes ☐ No
- ☐ Checklist for Research Involving Prisoners — ☐ Yes ☐ No
- ☐ Informed Consent Form — ☐ Yes ☐ No
- ☐ Letters of administrative approval — ☐ Yes ☐ No
- ☐ Grant application — ☐ Yes ☐ No
- ☐ C.V. of translator — ☐ Yes ☐ No
- ☐ Additional project materials

Specify: _____
_____
_____

Type of Review Requested (check one):

- ☐ Full committee review (submit originals and 14 copies of materials) — ☐ Yes ☐ No
- ☐ Expedited review--available only for projects without any direct human contact, such as projects using pre-existing data or specimens. (Submit originals and 3 copies of all materials) — ☐ Yes ☐ No

			THIS SHADED AREA FOR CPHS REVIEWERS ONLY Project Number: Reviewer Concurs:
1.	Is there adequate documentation in the protocol that the selection of subjects is equitable?	☐ Yes ☐ No	☐ Yes ☐ No
2.	Are adequate justifications in the protocol for the quantity of the data, the years & the variables being requested? Is no more than minimum necessary data requested?	☐ Yes ☐ No	☐ Yes ☐ No
3.	Is the data set to be linked with any other data sets?	☐ Yes ☐ No	☐ Yes ☐ No
	If yes, are all data sets identified and each of the variables listed and justified for each linkage?	☐ Yes ☐ No	☐ Yes ☐ No
4.	Will a third party be used to perform data matching?	☐ Yes ☐ No	☐ Yes ☐ No
	If yes, has evidence been provided of the third parties' ability to protect confidential, sensitive information?	☐ Yes ☐ No	☐ Yes ☐ No
5.	Will any of the following categories of vulnerable populations be involved?		☐ Yes ☐ No
	☐ Neonates (Submit Neonate Checklist except for data-only projects)		☐ Yes ☐ No
	☐ Prisoners (Submit Prisoner Checklist for all research)		☐ Yes ☐ No
	☐ Children (Submit Children Checklist required **except** for data-only projects)		☐ Yes ☐ No
	☐ Pregnant women or fetuses (Submit Pregnant Women and Fetuses Checklist **except** for data-only, survey or interview research)		☐ Yes ☐ No
6.	Is there adequate documentation in the protocol that research design is scientifically sound?	☐ Yes ☐ No	☐ Yes ☐ No
7.	Is there adequate documentation in the protocol that the risk to subjects is reasonable in relation to the anticipated benefits to the subjects/society?	☐ Yes ☐ No	☐ Yes ☐ No
8.	The risk level of this research is: Minimal ☐ Moderate ☐ High☐		☐ Yes ☐ No
9.	The risks of this research are (check all that apply):		
	Physical	☐	☐ Yes ☐ No
	Psychological	☐	☐ Yes ☐ No
	Social	☐	☐ Yes ☐ No
	Economic	☐	☐ Yes ☐ No
	Data security and confidentiality	☐	☐ Yes ☐ No
10.	Is an adequate plan presented in the protocol to protect data from improper use, including the implementation of effective administrative, physical and technical safeguards?	☐ Yes ☐ No	☐ Yes ☐ No
	• Locked cabinets or rooms?	☐ Yes ☐ No	☐ Yes ☐ No
	• Computer password protected?	☐ Yes ☐ No	☐ Yes ☐ No
	• Access is limited to authorized personnel only?	☐ Yes ☐ No	☐ Yes ☐ No
	• Data transported by secure carrier only?	☐ Yes ☐ No	☐ Yes ☐ No
	• Data not accessible to the Internet?	☐ Yes ☐ No	☐ Yes ☐ No
	• Laptop computers and portable electronic storage media	☐ Yes ☐ No	☐ Yes ☐ No

(e.g., CDs and USB devices) encrypted and never left unattended in cars or other unsecure sites?

Project Number:

			Reviewer Concurs
11.	Is there a commitment in the protocol that data will not be reused or provided to any unauthorized person or entity?	☐ Yes ☐ No	☐ Yes ☐ No
12.	Are social security numbers (SSNs) to be used?	☐ Yes ☐ No	☐ Yes ☐ No
	If yes, is adequate justification provided why other unique identifiers (not based on SSNs) cannot be used?	☐ Yes ☐ No	☐ Yes ☐ No
13.	Has a commitment been stated in the protocol to not publish information that could possibly lead to identification of individual subjects?	☐ Yes ☐ No	☐ Yes ☐ No
14.	Has an adequate plan been provided in the protocol to destroy or return the data as soon as it is no longer needed for research?	☐ Yes ☐ No	☐ Yes ☐ No
15.	Will the research likely involve small cells or small numbers?	☐ Yes ☐ No	☐ Yes ☐ No
	If yes, have appropriate and sufficient methods to protect the identity of individual subjects been described in the protocol?	☐ Yes ☐ No	☐ Yes ☐ No
16.	Is a waiver of patient authorization requested for HIPAA?	☐ Yes ☐ No	☐ Yes ☐ No
	If yes, has the following information been provided:		
	• A detailed description of the protected health information, including name of HIPAA covered entity(ies), name(s) of database(s), and variables?	☐ Yes ☐ No	☐ Yes ☐ No
	• Adequate evidence that the research could not be practicably conducted without access and use of protected health information?	☐ Yes ☐ No	☐ Yes ☐ No
	• Data protection measures (items 10-14 above) have been adequately described in the protocol?	☐ Yes ☐ No	☐ Yes ☐ No
17.	Is informed consent required?	☐ Yes ☐ No	☐ Yes ☐ No
	If yes**,** does the informed consent form provide:		
	• A description of the study (statement that the study involves research and explanation of the purpose, subject selection, duration, and procedures)?	☐ Yes ☐ No	☐ Yes ☐ No
	• A description of risks or discomfort?	☐ Yes ☐ No	☐ Yes ☐ No
	• A description of measures to protect confidentiality of subjects and records?	☐ Yes ☐ No	☐ Yes ☐ No
	• A description of benefits to subjects***/***others?	☐ Yes ☐ No	☐ Yes ☐ No
	• A disclosure of alternative procedures or treatments?	☐ Yes ☐ No	☐ Yes ☐ No
	• A statement of compensation or treatment for injury?	☐ Yes ☐ No	☐ Yes ☐ No
	• A statement of any potential conflicts of interest that may affect research results?	☐ Yes ☐ No	☐ Yes ☐ No
	• A statement of funding source of project?	☐ Yes ☐ No	☐ Yes ☐ No
	• A statement of whom to contact with questions about the research?	☐ Yes ☐ No	☐ Yes ☐ No
	• A statement of whom to contact about the rights of research subjects?	☐ Yes ☐ No	☐ Yes ☐ No
	• A statement of whom to contact regarding research-related injury?	☐ Yes ☐ No	☐ Yes ☐ No

			Project Number: Reviewer Concurs:
•	A statement of voluntary participation and the right to discontinue without penalty?	☐ Yes ☐ No	☐ Yes ☐ No
18.	Is a waiver of informed consent being requested?	☐ Yes ☐ No	☐ Yes ☐ No
	If yes, is there documentation in the protocol that:		
•	The risk to subjects is minimal?	☐ Yes ☐ No	☐ Yes ☐ No
•	The rights and welfare of subjects will not be adversely affected?	☐ Yes ☐ No	☐ Yes ☐ No
•	The research could not be practically carried out without a waiver?	☐ Yes ☐ No	☐ Yes ☐ No
•	When appropriate, the subjects will be provided with additional information later?	☐ Yes ☐ No	☐ Yes ☐ No
19.	Is a waiver of signed informed consent being requested?	☐ Yes ☐ No	☐ Yes ☐ No
	If yes, is there documentation in the protocol that:		
•	The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality OR	☐ Yes ☐ No	☐ Yes ☐ No
•	The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.	☐ Yes ☐ No	☐ Yes ☐ No
20	Are there potential conflicts of interest that could affect the quality of the research? ***If yes***, please specify:	☐ Yes ☐ No	☐ Yes ☐ No
21.	Is the project budget sufficient?	☐ Yes ☐ No	☐ Yes ☐ No
22.	Indicate the amount of funding project receives from each source listed below. **Federal $ _____ State $_____ Foundation $_____ Other $_____ Total: $ _____**		☐ Yes ☐ No
23.	Will an investigational drug(s) be used?	☐ Yes ☐ No	☐ Yes ☐ No
	If yes, is there an IND application?	☐ Yes ☐ No	☐ Yes ☐ No
24.	Will an investigational device be used?	☐ Yes ☐ No	☐ Yes ☐ No
	If yes, has it received FDA premarket approval, approval, or exemption?	☐ Yes ☐ No	☐ Yes ☐ No
25.	If an investigational drug or device will be used, have the procedures for adequately monitoring the safety of the subjects been described in the protocol ?	☐ Yes ☐ No	☐ Yes ☐ No
26.	Will translated documents be used?	☐ Yes ☐ No	☐ Yes ☐ No
	If yes,		
•	Specify language(s): _____		
•	Has adequate evidence of the translator's ability been provided?	☐ Yes ☐ No	☐ Yes ☐ No

27. List the formal names of State databases, such as the Cancer Registry, or specimens, such as blood spots, to be used in this project.

Department	**Name of Database(s)/Specimen(s)**
Dept. of Health Care Services	
Dept. of Public Health	
Office of Statewide Health Planning and Development	
Dept. of Mental Health	
Dept. of Developmental Services	
Dept. of Social Services	
Other (Specify)	

28. Check the box which indicates the nature of each department's involvement – e.g., funding, principal investigator (PI), research staff, or supplying human subjects (note that only subjects for which the State has direct responsibility, e.g., mental hospital patients, should be included
NOTE that only subjects for which the State has direct responsibility, e.g., mental hospital patients should be included.

☐ Yes ☐ No

Dept.	Funding	PI	Staff	Subjects
DHCS				
DPH				
OSHPD				
DMH				
DDS				
DSS				
Other				

Principal Investigator's Signature: _____**Date:** _____

CPHS Expedited Review Use Only (completed by Reviewer) Project #:_____

☐ Approved for Common Rule ☐ Common Rule approval deferred pending minor revisions
If approved, specify duration: 1 year ☐ or Other ☐ (specify)_____
☐ Approved for HIPAA waiver ☐ HIPAA waiver deferred pending revisions
☐ Approved for California Information Practices Act
☐ Referred to Full Committee

Reasons for referral to Full Committee or deferral of HIPAA waiver:

Comments and additional information:

If revisions required, check one of the following options:
☐ CPHS Reviewer must confirm revisions
☐ CPHS Staff may confirm revisions

CPHS Reviewer's Signature_____ Date:_____

CPHS staff has confirmed revisions with all reviewers: Initials:_____ Date: _____
CPHS staff has confirmed approval of all reviewers: Initials:_____ Date: _____